

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2004/001486

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. ⁷: A61N 1/365

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPAT. Keywords: heart, sounds, control, assist and similar terms

USPTO. Keywords: heart, sounds, r-wave

PUBMED. Keywords: heart, sounds, r-wave

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5792195 A (CARLSON et al.) 11 August 1998 See, especially: column 2, lines 8-49; column 3, lines 31-33; column 3, line 64 - column 4, line 62; claim 1	1-2, 4
P,X	US 6643548 B1 (MAI et al.) 4 November 2003 See, especially: column 11, lines 1-12; claims 8, 15, 17 and 35; Figures 1, 2, 4	1-2, 4-18, 25-34, 36
X	US 2003/0105497 A (ZHU et al.) 5 June 2003 See, especially: claim 13; Figure 4	1



Further documents are listed in the continuation of Box C



See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
17 December 2004

Date of mailing of the international search report
06 JAN 2005

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2004/001486

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 1998/014239 A (PACESETTER AB) 9 April 1998 See, especially: abstract; claims	1
X	EP 0080348 B2 (MEDTRONIC INC.) 7 September 1994 See, especially: abstract; claims; figures	1
X	US 5447523 A (SCHALDACH) 5 September 1995 See, especially: claims	1
X	US 4763646 A (LEKHOLM) 16 August 1988 See, especially, abstract; claims; figures	1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

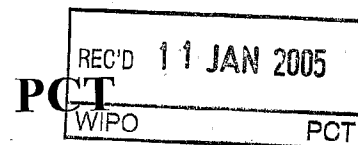
PCT/AU2004/001486

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member	
US	5792195		
US	6643548		
US	2003105497		
WO	9814239	EP	0936936
		US	6044299
EP	0080348	US	4428378
US	5447523	DE	3506791
		EP	0194224
		US	4919137
US	4763646	DE	3535504
		EP	0218009
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.			
END OF ANNEX			

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY



To:

SPRUSON & FERGUSON
GPO Box 3898
SYDNEY NSW 2001

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

<p>Date of mailing 06 JAN 2005 (day/month/year)</p>		
<p>Applicant's or agent's file reference 652460C</p>		
<p>FOR FURTHER ACTION See paragraph 2 below</p>		
<p>International application No. PCT/AU2004/001486</p>	<p>International filing date (day/month/year) 28 October 2004</p>	<p>Priority date (day/month/year) 31 October 2003</p>
<p>International Patent Classification (IPC) or both national classification and IPC Int. Cl. ⁷ A61N 1/365</p>		
<p>Applicant SUNSHINE HEART COMPANY PTY LTD et al</p>		

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty; inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

<p>Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929</p>	<p>Authorized Officer ROSEMARY LONGSTAFF Telephone No. (02) 6283 2637</p>
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2004/001486

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2004/001486

Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims 3, 5-36	YES
	Claims 1-2, 4	NO
Inventive step (IS)	Claims 3, 5-36	YES
	Claims 1-2, 4	NO
Industrial applicability (IA)	Claims 1-36	YES
	Claims	NO

2. Citations and explanations:

US 5792195 (D1)

US 2003/0105497 (D2)

WO 1998/014239 (D3)

EP 0080348 (D4)

US 5447523 (D5)

US 4763646 (D6)

Claim 1

The features of claim 1 are well-known and disclosed D1 to D6. Thus claim 1 is not novel and does not involve an inventive step over each of these documents.

Claims 2 and 4

D1 uses an accelerometer to sense the movement of the body structures of the patient. The sensed signals are filtered to obtain those signals within the audible range - ie heart sounds. In D1, R-wave signals are also detected and the difference in timing of the sound signal and the R-wave is used to control the timing of a cardiac stimulator. See, especially, column 2, lines 8-49 and claim 1 of D1 in this regard. D1 also discloses measurement of the time difference between the closing of the aortic valve, when sound S2 is produced, and the R-wave. See column 3, line 31-33 and column 3, line 64 - column 4, line 62. Thus D1 discloses all features of claims 2 and 4 of the current application and renders these claims not to be novel or involve an inventive step.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2004/001486

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
P,X US 6643548 B1	4 November 2003	6 April 2000	6 April 2000

US 6643548 (D7) was published 3 days after the priority date of the current application and has no family members. However D7 represents the closest of the cited art. Unlike D1, the heart sounds in D7 are measured via an acoustic sensor, equivalent to a microphone of claim 4 of the current application. Although D7 mainly shows a means of monitoring the progression of heart disease via the change in the S2 - R-wave time difference, column 11, lines 1-12 and claims 8 and 35 disclose the use of this data in adjusting pacing therapy. Were this document published in time, it could be used as a novelty or inventive step citation against claims 1-2, 4-18, 25-34 and 36 of the current application.

2. Non-written disclosures (Rules 43bis.1 and 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>
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